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09/883,069	06/14/2001	Shubh D. Sharma	70025-US29743	1720

EXAMINER-
WESSENDORF, TERESA D

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/883,069	Applicant(s) SHARMA ET AL.	
	Examiner T. D. Wessendorf	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *2,3 and 12-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-11, 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's acknowledgment of the finality of the restriction requirement as made final is noted.

Status of Claims

Claims 1-23 are pending.

Claims 2-3 and 12-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 1, 4-11 and 23 are under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1, 4-11 and 23 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility for reasons advanced in the last Office action.

Response to Arguments

Applicants argue that the utility of the library relates to library constituents that are capable of binding a target molecule of interest or mediating a biological activity of interest. It is further argued that the libraries are distinguished and characterized in that they provide a reverse turn structure as a consequence of metal ion complexation.

In response, applicants' arguments are all drawn to either the constituents contained in the library and the properties exhibited by these libraries. The utility asserted by applicants is a general utility i.e., mediating a biological activity that is as general as provided in the specification. This is not a specific utility. It is not clear as to the specific utility of the biological activity of a library possessing all the argued distinguishing and characterizing features of the library. Furthermore, as all compounds undergo binding to a target molecule, hence, binding is likewise, not a specific utility.

Applicants urge that utility of characteristic-specific combinatorial libraries is both disclosed and well-established. Applicants argue that "screening" in the sense of assay to determine biological activity or receptor specificity is a procedure frequently employed with combinatorial libraries, the

utility of combinatorial libraries is not for screening as such. Rather, the utility is to select and identify metallopeptides and metallo-constructs.

In reply, is this merely a difference in semantics? Screening is nothing more than selecting and identifying metallopeptides in the library.

Applicants rely on page 1, line 21 up to page 4, line 24 of the instant specification as describing the utility of the combinatorial libraries by citing the different literatures mentioned therein. It is further argued that PTO has consistently recognized the inherent utility of combinatorial libraries per se, based on the issued patents. Applicants further argue that applicants are not providing a "random" library in the sense of e.g., completely random peptide sequences, which as a result of protein folding, will have random or unpredicted three-dimensional structures. Applicants are providing a library with defined characteristics, in that the library members, each upon metal ion complexation, provide a reverse turn. Such reverse turn structures is argued then to provide a specific utility.

In response, the relevant pages 1-4 cited by applicants reveal also screening for drug discovery. Furthermore, it is well settled, that each case is treated on its own merits. It is

not clear as to applicants argued inherent utility of the combinatorial libraries. It is not seen how the instant claimed library could be different from random library, when the peptide contained in the libraries do not possess any structure. Rather, the claims recite any amino acids up to 100 containing any numbers of sulfur. This undefined peptide sequence can very well result in an improper folding and consequently in the lost of reverse turn property of said structurally undefined library. It is immaterial whether the library is random, as the issue lies in the utility of the library per se.

Applicants argue that the Examples of libraries targeted for melanocortin receptors and human neutrophil elastase are given in the specification.

In reply, it is not the library per se that binds to the target receptor, rather, the individual components present in the library. It is this individual component(s) that contain a specific and substantial utility.

Claims 1 and 4-11 are rejected under 35 U.S.C. 112, first paragraph, specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above. One skilled

in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-11, as amended, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons stated in the last Office action.

Response to Arguments

Applicants argue that with the amendments to the claim, the rejection has been overcome. Nevertheless, maintains that the proviso is supported in the as-filed specification, e.g., pages 18-19 and Figs. 1a - 1J.

In response, the present amendments are therefore not supported in the as-filed specification. It appears that the penultimate position of the S-containing residue should not be at the N or C or both termini. Hence, the broader claim that the S residue can be anywhere that includes the N or C and both termini is not supported in the as-filed specification. Because the library is described in terms rather, than in structure of the peptide sequence, hence, the claims as amended is confusing as to the exact location of each of the residues in the peptide sequence, let alone, in the library.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention.

In view of the amendments to the claims, the rejection of the claims under this statute no longer applies.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 4-11 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Sharma (U.S. 6,027,711) ('711 patent) for reasons set forth in the last Office action.

Response to Arguments

Applicants argue that the instant inventor, Sharma is also the named inventor in the '711 Patent. The owner of the '711 patent is the owner of the instant application. The owner of the

instant application has acquired the '711 patent owner. Therefore, the '711 patent is not "by another" under 102(e)(2).

In response, since applicants state that '711 patent has Sharma as a named inventor, hence under 102(e) this constitutes a prior art to the instant invention. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). [This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.]

Applicants argue that S-benzoyl and the like are not compatible with peptide synthesis and therefore are not orthogonal protecting groups.

In reply, Sharma does not limit the S-protecting group to S-benzoyl. Rather, Sharma recites other S protecting groups such as S-aminopropyl or aminoethyl (e.g., col. 37, lines 59 up to col. 38, lines 67). Thus, since this cys protected residue is included in the metal complexation hence, it is considered that it is an orthogonal protected S group. This group is solid phase compatible and removable since the desired complexation is achieved without deleterious effect to the complexed peptide.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-11 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hnatowich et al (U.S. 5,980,861) for reasons set forth in the last Office action.

Response to Arguments

Applicants argue that Hnatowich discloses only chelator compounds in which each amino acid residue binds to the metal ion. It only teaches tripeptide chelator sequences in which each amino acid is involved in complexation of a metal ion. It is further argued that Hnatowich then covalently complex the chelator sequences to the disclosed biologically active sequences, such as the disclosed nucleic acids. It is argued that this distinction is critical. Applicants' invention conformationally constrained sequences are specific to a target of interest. In Hantowich the only objective is discovery of the best chelate for a specific chelate application.

In response, Hnatowich discloses not only a tripeptide, as argued. Rather, a peptide containing said tripeptide attached to a ***peptide***-nucleic acid and not solely to nucleic acid. Applicants appear to limit the Hnatowich teachings that are suitable to applicants. Applicants' argument as to the conformational constrained on the instant sequences is not commensurate in scope with the claims, when the claims recite a single sulfur atom. Furthermore, whether the objective of Hnatowich is different from the instant one is immaterial, since Hnatowich discloses the similar compound, as claimed.

Hnatowich is argued not to teach S-orthogonal protecting groups as defined in the specification. The S-acetyl protecting group disclosed by Hnatowich is not compatible with the methods of peptides synthesis. The S-acetyl group is unstable and therefore not usable during ***certain*** peptide synthesis steps. The used of conventional peptide synthesis reagents, such as piperidine, is specifically contemplated by applicants. And, is a specific requirement of an orthogonal S-protecting group that it be compatible with methods of peptide chemistry.

In reply, the specification does not define orthogonal protecting groups. Rather, merely lists the protecting groups included by said terminology. However, said protecting group or selection from the conventional ones would be within the

ordinary skill in the art, specifically Fmoc. It is well known in the art that Fmoc has substituted many protecting groups during synthesis. This is because Fmoc is known to be more stable during chemical synthesis and removable subsequent to synthesis, if desired. [Solid phase synthesis has long been automated that the choice of protecting groups is no longer consider problematic).

Applicants refer to a copy of the Green reference that established that it is known in the art that S-acetyl protecting groups are incompatible with conventional peptide synthesis.

In response, the copy is not evident on the record. As stated above, solid phase synthesis has markedly advanced that one skilled in the art knows which protecting groups to apply in the synthesis of a certain peptide. Applicants further argue that claim 1 is amended to recite each library member "consists" of the defined amino acid sequences and excludes the nucleic acid compositions of Hnatowich.

In reply, the claim does not consist of ***defined*** amino acids, as no structure of the residues is defined therein. As stated above, Hnatowich teaches that the nucleic acids are not solely nucleic acids but ***peptide*** containing nucleic acid. Thus, even with the "consisting" words, the peptide-nucleic acid of Hnatowich is not precluded.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 2-3 and 12-22 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
November 14, 2003